財桂生物股份有限公司
Katsura Biological Corp.

Viral DNA/RNA Respi KF Kit (96)

(for use with the KingFisher Flex instrument)

CE IVD

REF **301112**

Σ 96 assays

A. Intended Use

The **Viral DNA/RNA Respi KF Kit** uses magnetic bead technology for rapid and reliable extraction of high-quality DNA and RNA from biological **samples collected in transport medium, such as nasal & throat swabs, BAL, sputum etc.**

The product is intended to be used by professional users, such as technicians and physicians, that are trained in molecular biological techniques, and it is intended for in vitro diagnostic use.

B. Principles of the Procedure

The Viral DNA/RNA Respi KF Kit procedure comprises 4 steps (lyse, bind, wash, elute) and is carried out fully automated, using pre-filled 96-well extraction plates on the KingFisher Flex extraction instrument. The procedure is designed to eliminate the potential for sample-to-sample cross-contamination and allows safe handling of potentially infectious samples.

Sample input volume is 200 µl, and elution volume is 100 µl.

Purified nucleic acids can be used for downstream applications such as real-time PCR, next generation sequencing etc.

C. Storage Conditions

The Viral DNA/RNA Respi KF Kit is stable at room temperature (15°C to 25°C), and it can be stored until the expiration date printed on the box label.

D. Kit Components

Item	Qty.	
Extraction Plate	4	96-well extraction plates pre-filled with reagent buffers
96-rod comb	1	96-channel grid for use with the KingFisher Flex
Package Insert	1	Instructions for use for operator

Extraction Plate Contents

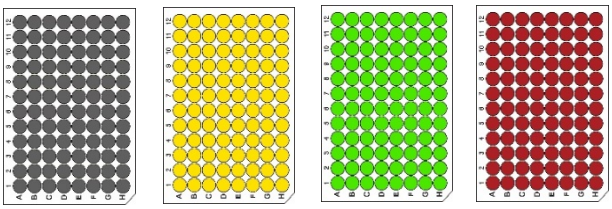

Plate 1 Plate 2 Plate 3 Plate 4

- Lysis Buffer JS-3 with magnetic beads; 680 µl/well
- Wash Buffer W1B; 700 µl/well
- Wash Buffer W2B; 800 µl/well
- Elution Buffer EL1; 100 µl/well

E. Limitations and General Precautions

- This product is intended for use by trained personnel only.
- Wear disposable gloves, laboratory coat and eye protection when handling samples and reagents. Wash hands thoroughly thereafter.
- Process all samples on clean bench or in biosafety cabinet.
- The kit is used for Viral DNA and RNA isolation; therefore, use sterile pipette tips with filters or autoclaved tips tubes.
  Replace the tip for every process step.
- Magnetic beads may occasionally appear in the elution buffer. If so, please avoid the magnetic beads while transferring the extracted product.
- The KingFisher Flex should be disinfected after any extraction procedure, following the steps described in the manufacturers' handbook.
- Do not use the kit after its expiration date.
- Elution buffer has been pre-filled in extraction plate no. 4.
  Users should expect up to 20% loss from the initial volume due to evaporation by elution heating in the extraction process.

F. Nucleic Acid Extraction Procedure

IMPORTANT NOTE:

For running an extraction with the Viral DNA/RNA Respi KF Kit on the **KingFisher Flex** please refer to the instrument handbook and the **BindIt Software User Manual** for creating a **user-defined extraction protocol**. The standard protocol details are listed in Section F.

Ensure that the instrument is set up for the extraction using 96-well deep well plates.

- Unpack the 96-rod comb and place it onto an empty 96-well deep well plate.
- Place the 96-rod comb plate to its designated position on the instrument.
- Remove the extraction plate no. 1 (lysis plate) from the kit and invert the plate several times to re-suspend the magnetic beads. Gently swirl the plate to gather the solution to the bottom of the wells, or spin down the plate at 500rpm for 1 min.
- Carefully remove the sealing foil, take care to avoid spillage.
- Transfer **200 µl of sample** in transport medium to the wells of the lysis plate. One sample = one well.
  Note: The instrument runs 96 sample extractions per run, the reagent plates cannot be re-used.
- Place the prepared extraction plate no. 1 to its designated position on the instrument.
- Remove the sealing foil from plates 2 – 4 and place them to their

designated positions on the instrument.
- Confirm the deck positions of the plates with the positions set in the user-defined protocol, then start the run.
- After completion of the run immediately remove the Elution plate (extraction plate no. 4) from the instrument.
- Carefully transfer the **extracted nucleic acid** to the final nuclease-free tube/plate of choice for further downstream analysis or final storage. Store the eluates at -20°C in a **NON-frost-free** freezer, to avoid freeze-thaw cycles that may cause sample degradation.

F. Standard Extraction Protocol

Protocol Name: **Viral DNA/RNA RESPI KF**									
Plate No.	Name	Deck position	Process Step	Standby	Mix 1 - 30 min.	Volume	Mix Speed	Mag. 0 - 120 sec.	Temp. °C
1	Lysis	1	Lysis	0	5	880	Fast	30	40
2	Wash1	2	Wash1	0	1	700	Fast	30	
3	Wash2	3	Wash2	0	1	800	Fast	30	
4	Elution	4	Elution	5	5	100	Fast	60	80
		3	Release Bead	0	1	600	Fast	0	
none	96-rod comb	5	Pick up comb						

Danger!
Contains Guanidine thiocyanate
Contains Guanidine hydrochloride

H332: Harmful if inhaled.
H312: Harmful in contact with skin.
H302: Harmful if swallowed.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H412: Harmful to aquatic life with long lasting effect.

P260: Do not breathe mist/vapors/spray.
P262: Do not get in eyes, on skin, or on clothing.
P264: Wash thoroughly after handling.
P273: Avoid release to the environment.
P280: Wear protective gloves/protective clothing/eye protection/ face protection.

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